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Box Missing Parts, Assistant Commissioner for Patents, Washington, D.C. 20231, on April 22, 2002.

Vicki L. Andrews
Vicki L. Andrews

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Roger DELUSIGNAN and Geoffrey DAVIS

Serial No.: 10/042,766

Filing Date: January 8, 2002

For: SYSTEMS AND METHODS FOR
EVALUATING PATIENT-SPECIFIC
INFORMATION AND PROVIDING
PATIENT MANAGEMENT
RECOMMENDATIONS FOR
HEALTHCARE PROVIDERS

Examiner: To be Assigned

Group Art Unit: 3736

COPY OF PAPERS
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PRELIMINARY AMENDMENT

Box Missing Parts
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This is in response to Notice to file missing parts of nonprovisional application dated February 8, 2002, for which a response was set to expire on April 8, 2002. The Applicants respectfully request one month of extension of time. Required fee is submitted herewith. Accordingly, this response is timely filed.

Please enter the following preliminary amendment and remarks.

I. AMENDMENT

Prior to examination of the above-captioned application please amend the patent application as follows:

In the Specification:

Please delete paragraphs 9-12 on page 3.

Please delete Figures 2-5 in their entirety.

Please replace the paragraph [23], beginning at page 6, with the following paragraph [23]:

--Once the population of patients has been defined, personal patient information is collected from the population of patients. The source of personal patient information is queried to gather information that is generally recognized by professional organizations as being associated with the preselected medical condition. In a preferred embodiment, the source of personal information is the patient themselves. By way of example, Table 1 as shown below is a model "risk assessment survey" for coronary artery disease, which may also be referred to herein as an "input collection tool".--

Immediately following new paragraph [23] please insert the following Table 1:

Table 1

CAD Program – Risk Assessment Survey

☐ Section I – Patient/Physician Information

Please complete the following

| | | |
|-------------------------------------|------------------------------|-----------------------------|
| Patient Name: | | |
| What is the name of your physician: | Phone number if available: | |
| Is your physician a cardiologist: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

☐ Section II – Predictors of Coronary Artery Disease Risk

Please complete the following

| | | |
|--|--|--|
| What is your LDL cholesterol level ("bad" cholesterol) ? | <input type="checkbox"/> More than 100 mg/dL | <input type="checkbox"/> 100 mg/dL or less |
| What is your HDL cholesterol level ("good" cholesterol)? | <input type="checkbox"/> More than 35 mg/dL | <input type="checkbox"/> 35 mg/dL or less |
| What is your triglycerides level? | <input type="checkbox"/> More than 200 mg/dL | <input type="checkbox"/> 200 mg/dL or less |
| Is your blood pressure 130/80 or higher? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you currently smoke cigarettes? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you have diabetes or do you take medicines to control your blood glucose? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Has your doctor told that you have problems with the arteries (blood vessels) in your heart? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Have you ever had a heart attack? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Has your doctor told you that you have an enlarged heart or heart failure? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Have you been admitted to the hospital or visited the emergency department in the previous 12 months for a heart problem? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Did a first-degree relative (father, mother, brother, sister, son or daughter) have a heart attack before the age of 55 years? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Please replace the paragraph [24], beginning at page 6, with the following paragraph [24]:

--As shown, the type of information collected in the risk assessment survey can be adapted for use in assessing a patient's risk of having or developing a given medical condition. Collectively, categorizing the risk, for example as low-medium-high, as well as establishing that the patient most likely already has the medical condition, is referred to herein as "risk assessment". For example, the survey depicted in Table 1 includes the following question:

"Has your doctor told you that you have problems with the arteries (blood vessels) in year heart?"--

Please replace the paragraph [25], beginning at page 7, with the following paragraph [25]:

--The next step in the system of the present invention is the input and processing of the personal patient information by the central system to generate the patient analysis outcome. The outcome can take any form, e.g., outcome that is visible on a computer screen or which may be printed and sent by mail or by fax to the healthcare provider. A sample letter that is sent to a physician following input and processing of personal patient information in a CAD system is shown below.

Dear [Healthcare Provider]:

<<customer>> is pleased to introduce the LifeMasters[®] Coronary Artery Disease (CAD) Primary Prevention program, a disease management intervention for <<customer>> patients. This innovative program was established to reduce the incidence of angina, myocardial infarctions and strokes in patients at high risk for coronary artery disease (CAD).

LifeMasters' goal is to identify individuals who are at high risk for CAD and then support physicians in their care management of these patients. A high risk patient for CAD is defined by the American Heart Association as any individual with two or more cardiovascular risk factors (hypertension, hyperlipdemia, positive family history for CAD, current smoker, etc.) or having diabetes. Once a high risk patient is identified through an evidence-based risk assessment survey, the patient is enrolled in the following support program that facilitates the "best practice" management of that patient's CAD risk factors.

This primary prevention program for at risk CAD patients consists of the following components:

- 1) All patients who are 45 years of age or older are identified via the health plan's membership data;
- 2) These patients are sent the LM CAD risk assessment survey;
- 3) Upon completion of these surveys, patients are identified who are at high risk for the development of coronary artery disease (CAD) as defined by the American Heart Association;
- 4) In order to promote best practice clinical management of these at-risk patients, the identified personal physician of these patients is sent a follow-up LM CAD data collection tool for completion of patient-specific clinical data;
- 5) Upon return of this CAD data collection tool back to LM, the physician is sent a one page, patient-specific "best practice" set of recommendations based on the American Cardiology/ American Heart Association clinical guidelines;
- 6) This patient-specific CAD data collection tool and recommendation report is then sent to the physician every six months so the physician can longitudinally track the care management progress of his/her at-risk patients for CAD.

Enclosed with this cover letter is a CAD data collection tool for each of the patients in your practice that have been identified as high risk for the development of CAD. We want to thank you beforehand for your timely completion of these clinical data forms and hope they will be helpful in tracking the care of your patients.

Please contact _____ with questions or feedback about the program.

We appreciate your support and look forward to a successful program.

Sincerely,

LifeMasters Supported SelfCare, Inc.

Enclosure: CAD Data Collection Tool

As can be seen, the outcome, which would be attached to the letter, may be as simple as the identification of individual patients within the patient population that are determined to have a "high risk" of contracting the medical condition based on the information that was supplied. Other types of outcome may include a more complete risk assessment of the entire population, such that individual members are categorized as having no risk, low risk, medium risk, high risk, or they are identified as already most likely having the medical condition.--

Please replace the paragraph [27], beginning at page 7, with the following paragraph [27]:

--Accordingly, shown below in Table 2, is an exemplary input collection device, a "Data Collection Form", for use in a CAD system. Included therein are queries that are chosen according to clinical guidelines for customizing the recommendations outcome in a way that will be most useful to the healthcare provider in treating a CAD patient. For convenience, if the recipient of the patient analysis outcome and the entity from which the patient management information input is sought are the same, then the steps of providing this outcome and seeking input can take place simultaneously.--

Immediately following new paragraph [27], please insert the following Table 2.

Table 2
CAD Program – Data Collection Form

Instructions:**Fill in the data collection date****Complete Section I: Correct the current information and/or supply missing information, as applicable****Complete Section II: Check the “Yes” or “No” checkboxes for all items as applicable****Complete Section III: Check the “Yes” or “No” checkboxes for all items as applicable****Date:** _____

| | | | | |
|---|--|--|--------------------------|--------------------------|
| Section 1 – Patient/Physician Information | | | | |
| Patient Name: | | AGE: | DOB: | |
| Height: | Weight: | | | |
| Physician Name: | | | | |
| Physician Address: | | | | |
| Physician Phone Number: | | FAX Number: | Email: | |
| Section II – Medical History /Risk Factors | | | | |
| | | | Yes | No |
| History of MI | Yes <input type="checkbox"/> No <input type="checkbox"/> | Hospitalization for MI in last 12 months | | <input type="checkbox"/> |
| History of CABG or angioplasty | | | | <input type="checkbox"/> |
| History of angina pectoris | | | | <input type="checkbox"/> |
| History of positive stress test (ECG stress test or echocardiography stress test) | | | | <input type="checkbox"/> |
| History of diabetes | | | | <input type="checkbox"/> |
| Most recent HbA1c level is $\geq 8\%$ | | | | <input type="checkbox"/> |
| History of hypertension | Yes <input type="checkbox"/> No <input type="checkbox"/> | Is hypertension well controlled (BP $\geq 130/85$, if diabetes BP $> 130/80$) | | <input type="checkbox"/> |
| History of hyperlipidemia | | | | <input type="checkbox"/> |
| LDL-c within the past 12 months | Yes <input type="checkbox"/> No <input type="checkbox"/> | Is the LDL-c < 100 mg/dL? | | <input type="checkbox"/> |
| Triglycerides within the past 12 months | Yes <input type="checkbox"/> No <input type="checkbox"/> | Is the triglycerides < 200 mg/dL? | | <input type="checkbox"/> |
| HDL-c within past 12 months | Yes <input type="checkbox"/> No <input type="checkbox"/> | Is the HDL-c ≥ 40 mg/dL | | <input type="checkbox"/> |
| Current smoker | | | | <input type="checkbox"/> |
| If the patient is a current smoker, is smoking cessation counseling given at every clinic appointment | | | | <input type="checkbox"/> |
| Section III – Medication Profile | | | | |
| | | | Yes | No |
| Is the patient on antiplatelet therapy? | | | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the patient on beta blocker therapy (if history of MI present)? | | | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the patient on statin therapy? | | | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the patient on nicotinic acid, fibrate or resin therapy | | | <input type="checkbox"/> | <input type="checkbox"/> |

Please replace the paragraph [28], beginning at page 8, with the following paragraph [28]:

--The next step in the system is the input and processing of the patient management information by the central system to generate the recommendations outcome. Shown below in Table 3 is a sample recommendations outcome for a CAD patient. Unlike other methods designed to diagnose and prognose a patient's condition, the recommendations outcome provides a summary of patient-specific information and evidence-based clinical recommendations for the patient's ongoing management. Accordingly, the recommendations outcome is based on previous research-studies and clinical evidence that individuals whose input meets certain criteria would be most appropriately managed according to certain guidelines. Any "diagnostic" information about a patient is provided directly from the patient or healthcare provider when the patient-specific input is collected. Likewise, any prognostic analysis of the patient on the basis of the information collected is left completely to the healthcare provider.--

Table 3

CAD Program Recommendations

Report Date: _____ CAD Clinical Recommendations for John Doe (id:17) Based on data collected _____

Past Medical History: (1) MI (within last 12 months), (2) Angina, (3) Diabetes, and (4) Hypertension
These recommendations are intended to assist physicians in clinical decision making by describing a range of generally acceptable approaches for the management, or prevention of CAD.

| Indicator | Goal | Goal Met | Recommendations |
|----------------------------|-------------------------------------|-----------|---|
| MI (within last 12 months) | β -blocker therapy initiated | No | Post Recent MI History of MI within last 12 months. No β -blocker medication reported. The ACC/AHA recommends the initiation of β -blocker therapy ¹ . |
| Antiplatelet Therapy | Antiplatelet therapy initiated | Yes | Antiplatelet Therapy Antiplatelet therapy reported. No additional recommendations. |
| Hypertension | BP < 130/85 (< 130/80 for diabetes) | No | Hypertension BP \geq 130/85 reported. For uncomplicated hypertension, the JNC VI recommends the use of β -blocker and/or diuretics as first line therapy. As recommended by the ACC/AHA guidelines, for patients with known CAD titrate medication regimen to BP \leq 130/85 (for diabetic patients, titrate BP to < 130/80). If patient also diagnosed with diabetes or CHF, consider ACE inhibitor medication as first line therapy. If patient has NYHA class II or III CHF, also consider adding β -blocker therapy ⁴ . |
| LDL-c | LDL-c < 100 mg/dL | No | Elevated LDL-c LDL-c level \geq 100 mg/dL reported and patient on statin therapy. Recommend either titrating current medication, adding another lipid lowering medication or changing to alternative therapeutic regimen in order to achieve ACC/AHA recommended LDL-c level of < 100 mg/dL ^{1,2} . |
| Triglycerides | Triglycerides < 200 mg/dL | No | Elevated Triglycerides Triglycerides level > 200 mg/dL reported. The ACC/AHA recommends gemfibrozil or niacin therapy for patients with HDL-c < 40 mg/dL and triglycerides level > 200 mg/dL, if no contraindications ^{1,2} . |
| HDL-c | HDL-c \geq 40 | No | Low HDL-c HDL-c level < 40 mg/dL reported. Currently on lipid lowering medication. If accompanying triglycerides levels > 200 mg/dL, the ACC/AHA Recommends gemfibrozil or niacin therapy ^{1,2} . |
| Diabetes | HbA1c < 8% | No | <ul style="list-style-type: none"> Diabetes HbA1c \geq 8% reported. The ADA recommends a HbA1c goal < 7%. The findings of the DCCT and UKPDS studies indicate that strict blood glucose control will prevent up to 70% of significant, kidney, eye, and neurological complications. These studies also indicate that every percentage point decrease in an individual's HbA1c level there is a 25% reduction in diabetes-related deaths, a 7% reduction in all-cause mortality and an 18% reduction in combined fatal and nonfatal myocardial infarction³. |
| Current Smoker | Non-smoker | Not Known | Smoking Cessation No response received. Assess the patient's smoking status and offer appropriate interventions if currently smoking ⁵ . |
| Obesity | BMI < 27 Kg/m ² | No | Regular exercise may reduce the risk of CAD Recommend low cholesterol, low fat diet |

¹AHA/ACC/ACP-ASIM Guidelines for the Management of Patients with Chronic Unstable Angina and Acute MI (2000)

²National Cholesterol Education Program (NCEP – ATPIII) – 2001

³American Diabetes Association 2001

⁴The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI) – 1997

⁵Treating Tobacco Use and Dependence, U.S. Department of Health and Human Services Clinical Guidelines – 2000—

II. REMARKS

In the Notice to file Missing Parts of nonprovisional application the drawings have been objected to because of the failure to comply with the drawings rules. More specifically, it was stated that more than one figure is present and each figure is not labeled "Fig." with a consecutive Arabic numeral or an Arabic numeral and capital letter in the English alphabet (37 CFR 1.84(u)(1)). It was also stated that the drawings contain excessive text (37 CFR 1.84(o)).

To eliminate these objections and to put the information, presented in Figures 2-5 as filed, into more suitable and presentable form, the Applicants have amended the specification by incorporating Figures 2-5 into the body of the specification. Accordingly, this amendment does not constitute new matter.

III. SUMMARY


Attached hereto is a marked version of the changes made to the specification by the current amendment. The attached page is captioned "Version with markings to show changes made."

In the unlikely event that the patent office determines that extensions and/or other relief is required, applicant petition for any required relief including extensions of time and authorize the assistant commissioner to charge the cost of such petitions and/or fees due to our deposit account no. 03-1952 under order no. 355592000200. The assistant commissioner is not authorized to charge the cost of the issue fee to the deposit account.

Respectfully submitted,

April 22, 2002

By:


Laurie A. Axford
Registration No. 35,053

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Suite 500
San Diego, California 92130-2332
Telephone: (858) 720-5133
Facsimile: (858) 720-5125

VERSION WITH MARKINGS TO SHOW CHANGES MADE**In the Specification:**

Paragraphs 9-12 on page 3 have been deleted.

Figures 2-5 have been deleted in their entirety.

The paragraph [23], beginning at page 6, has been amended as follows:

Once the population of patients has been defined, personal patient information is collected from the population of patients. The source of personal patient information is queried to gather information that is generally recognized by professional organizations as being associated with the preselected medical condition. In a preferred embodiment, the source of personal information is the patient themselves. By way of example, [Figure 2] Table 1 as shown below is a model "risk assessment survey" for coronary artery disease, which may also be referred to herein as an "input collection tool".

Table 1**CAD Program – Risk Assessment Survey****Section 1 – Patient/Physician Information****Please complete the following**

| | | |
|---|--|---|
| <u>Patient Name:</u> | | |
| <u>What is the name of your physician:</u> | <u>Phone number if available:</u> | |
| <u>Is your physician a cardiologist:</u> | <input type="checkbox"/> <u>Yes</u> | <input type="checkbox"/> <u>No</u> |

Section II – Predictors of Coronary Artery Disease Risk**Please complete the following**

| | | |
|--|--|--|
| <u>What is your LDL cholesterol level ("bad" cholesterol) ?</u> | <input type="checkbox"/> <u>More than 100 mg/dL</u> | <input type="checkbox"/> <u>100 mg/dL or less</u> |
| <u>What is your HDL cholesterol level ("good" cholesterol)?</u> | <input type="checkbox"/> <u>More than 35 mg/dL</u> | <input type="checkbox"/> <u>35 mg/dL or less</u> |
| <u>What is your triglycerides level?</u> | <input type="checkbox"/> <u>More than 200 mg/dL</u> | <input type="checkbox"/> <u>200 mg/dL or less</u> |
| <u>Is your blood pressure 130/80 or higher?</u> | <input type="checkbox"/> <u>Yes</u> | <input type="checkbox"/> <u>No</u> |
| <u>Do you currently smoke cigarettes?</u> | <input type="checkbox"/> <u>Yes</u> | <input type="checkbox"/> <u>No</u> |
| <u>Do you have diabetes or do you take medicines to control your blood glucose?</u> | <input type="checkbox"/> <u>Yes</u> | <input type="checkbox"/> <u>No</u> |
| <u>Has your doctor told that you have problems with the arteries (blood vessels) in your heart?</u> | <input type="checkbox"/> <u>Yes</u> | <input type="checkbox"/> <u>No</u> |
| <u>Have you ever had a heart attack?</u> | <input type="checkbox"/> <u>Yes</u> | <input type="checkbox"/> <u>No</u> |
| <u>Has your doctor told you that you have an enlarged heart or heart failure?</u> | <input type="checkbox"/> <u>Yes</u> | <input type="checkbox"/> <u>No</u> |
| <u>Have you been admitted to the hospital or visited the emergency department in the previous 12 months for a heart problem?</u> | <input type="checkbox"/> <u>Yes</u> | <input type="checkbox"/> <u>No</u> |
| <u>Did a first-degree relative (father, mother, brother, sister, son or daughter) have a heart attack before the age of 55 years?</u> | <input type="checkbox"/> <u>Yes</u> | <input type="checkbox"/> <u>No</u> |

The paragraph [24], beginning at page 6, has been amended as follows:

As shown, the type of information collected in the risk assessment survey can be adapted for use in assessing a patient's risk of having or developing a given medical condition. Collectively, categorizing the risk, for example as low-medium-high, as well as establishing that the patient most likely already has the medical condition, is referred to herein as "risk assessment". For example, the survey depicted in [Figure 2] Table 1 includes the following question:

"Has your doctor told you that you have problems with the arteries (blood vessels) in year heart?"

The paragraph [25], beginning at page 7, has been amended as follows:

The next step in the system of the present invention is the input and processing of the personal patient information by the central system to generate the patient analysis outcome. The outcome can take any form, e.g., outcome that is visible on a computer screen or which may be printed and sent by mail or by fax to the healthcare provider. A sample letter that is sent to a physician following input and processing of personal patient information in a CAD system is shown [in Figure 3] below.

Dear [Healthcare Provider]:

<<customer>> is pleased to introduce the LifeMasters[®] Coronary Artery Disease (CAD) Primary Prevention program, a disease management intervention for <<customer>> patients. This innovative program was established to reduce the incidence of angina, myocardial infarctions and strokes in patients at high risk for coronary artery disease (CAD).

LifeMasters' goal is to identify individuals who are at high risk for CAD and then support physicians in their care management of these patients. A high risk patient for CAD is defined by the American Heart Association as any individual with two or more cardiovascular risk factors (hypertension, hyperlipdemia, positive family history for CAD, current smoker, etc.) or having diabetes. Once a high risk patient is identified through an evidence-based risk assessment survey, the patient is enrolled in the following support program that facilitates the "best practice" management of that patient's CAD risk factors.

This primary prevention program for at risk CAD patients consists of the following components:

- 1) All patients who are 45 years of age or older are identified via the health plan's membership data;
- 2) These patients are sent the LM CAD risk assessment survey;
- 3) Upon completion of these surveys, patients are identified who are at high risk for the development of coronary artery disease (CAD) as defined by the American Heart Association;
- 4) In order to promote best practice clinical management of these at-risk patients, the identified personal physician of these patients is sent a follow-up LM CAD data collection tool for completion of patient-specific clinical data;
- 5) Upon return of this CAD data collection tool back to LM, the physician is sent a one page, patient-specific "best practice" set of recommendations based on the American Cardiology/ American Heart Association clinical guidelines;
- 6) This patient-specific CAD data collection tool and recommendation report is then sent to the physician every six months so the physician can longitudinally track the care management progress of his/her at-risk patients for CAD.

Enclosed with this cover letter is a CAD data collection tool for each of the patients in your practice that have been identified as high risk for the development of CAD. We want to thank you beforehand for your timely completion of these clinical data forms and hope they will be helpful in tracking the care of your patients.

Please contact _____ with questions or
feedback about the program.

We appreciate your support and look forward to a successful program.

Sincerely,

LifeMasters Supported SelfCare, Inc.

Enclosure: CAD Data Collection Tool

As can be seen, the outcome, which would be attached to the letter, may be as simple as the identification of individual patients within the patient population that are determined to have a "high risk" of contracting the medical condition based on the information that was supplied. Other types of outcome may include a more complete risk assessment of the entire population, such that individual members are categorized as having no risk, low risk, medium risk, high risk, or they are identified as already most likely having the medical condition.

The paragraph [27], beginning at page 7, has been amended as follows:

Accordingly, shown below in [Figure 4] Table 2, is an exemplary input collection device, a "Data Collection Form", for use in a CAD system. Included therein are queries that are chosen according to clinical guidelines for customizing the recommendations outcome in a way that will be most useful to the healthcare provider in treating a CAD patient. For convenience, if the recipient of the patient analysis outcome and the entity from which the patient management information input is sought are the same, then the steps of providing this outcome and seeking input can take place simultaneously.

Table 2
CAD Program – Data Collection Form

Instructions:**Fill in the data collection date****Complete Section I:** **Correct the current information and/or supply missing information, as applicable****Complete Section II:** **Check the “Yes” or “No” checkboxes for all items as applicable****Complete Section III:** **Check the “Yes” or “No” checkboxes for all items as applicable****Date:** _____

| | | | |
|--|--|---|--------------------------|
| Section 1 – Patient/Physician Information | | | |
| Patient Name: | | AGE: | DOB: |
| Height: | Weight: | | |
| Physician Name: | | | |
| Physician Address: | | | |
| Physician Phone Number: | FAX Number: | Email: | |
| Section II – Medical History /Risk Factors | | | |
| | | Yes | No |
| History of MI | Yes <input type="checkbox"/> No <input type="checkbox"/> | Hospitalization for MI in last 12 months | |
| History of CABG or angioplasty | | <input type="checkbox"/> | <input type="checkbox"/> |
| History of angina pectoris | | <input type="checkbox"/> | <input type="checkbox"/> |
| History of positive stress test (ECG stress test or echocardiography stress test) | | <input type="checkbox"/> | <input type="checkbox"/> |
| History of diabetes | | <input type="checkbox"/> | <input type="checkbox"/> |
| Most recent HbA1c level is > 8% | | <input type="checkbox"/> | <input type="checkbox"/> |
| History of hypertension | Yes <input type="checkbox"/> No <input type="checkbox"/> | Is hypertension well controlled (BP > 130/85, if diabetes BP > 130/80) | |
| History of hyperlipdemia | | <input type="checkbox"/> | <input type="checkbox"/> |
| LDL-c within the past 12 months | Yes <input type="checkbox"/> No <input type="checkbox"/> | Is the LDL-c < 100 mg/dL ? | |
| Triglycerides within the past 12 months | Yes <input type="checkbox"/> No <input type="checkbox"/> | Is the triglycerides < 200 mg/dL? | |
| HDL-c within past 12 months | Yes <input type="checkbox"/> No <input type="checkbox"/> | Is the HDL-c > 40 mg/dL | |
| Current smoker | | <input type="checkbox"/> | <input type="checkbox"/> |
| If the patient is a current smoker, is smoking cessation counseling given at every clinic appointment | | <input type="checkbox"/> | <input type="checkbox"/> |
| Section III – Medication Profile | | | |
| | | Yes | No |
| Is the patient on antiplatelet therapy? | | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the patient on beta blocker therapy (if history of MI present)? | | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the patient on statin therapy? | | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the patient on nicotinic acid, fibrate or resin therapy | | <input type="checkbox"/> | <input type="checkbox"/> |

The paragraph [28], beginning at page 8, has been amended as follows:

The next step in the system is the input and processing of the patient management information by the central system to generate the recommendations outcome. Shown [in Figure 5] below in Table 3 is a sample recommendations outcome for a CAD patient. Unlike other methods designed to diagnose and prognose a patient's condition, the recommendations outcome provides a summary of patient-specific information and evidence-based clinical recommendations for the patient's ongoing management. Accordingly, the recommendations outcome is based on previous research-studies and clinical evidence that individuals whose input meets certain criteria would be most appropriately managed according to certain guidelines. Any "diagnostic" information about a patient is provided directly from the patient or healthcare provider when the patient-specific input is collected. Likewise, any prognostic analysis of the patient on the basis of the information collected is left completely to the healthcare provider.

Table 3

CAD Program Recommendations

Report Date: CAD Clinical Recommendations for John Doe (id:17) **Based on**
data collected

Past Medical History: (1) MI (within last 12 months), (2) Angina, (3) Diabetes, and (4) Hypertension
 These recommendations are intended to assist physicians in clinical decision making by describing a range of generally acceptable approaches for the management, or prevention of CAD.

| Indicator | Goal | Goal Met | Recommendations |
|----------------------------|---|-----------|--|
| MI (within last 12 months) | <u>β-blocker therapy initiated</u> | No | Post Recent MI History of MI within last 12 months. No β -blocker medication reported. The ACC/AHA recommends the initiation of β -blocker therapy ¹ . |
| Antiplatelet Therapy | <u>Antiplatelet therapy initiated</u> | Yes | Antiplatelet Therapy Antiplatelet therapy reported. No additional recommendations. |
| Hypertension | <u>BP < 130/85 (< 130/80 for diabetes)</u> | No | Hypertension BP \geq 130/85 reported. For uncomplicated hypertension, the JNC VI recommends the use of β -blocker and/or diuretics as first line therapy. As recommended by the ACC/AHA guidelines, for patients with known CAD titrate medication regimen to BP < 130/85 (for diabetic patients, titrate BP to < 130/80). If patient also diagnosed with diabetes or CHF, consider ACE inhibitor medication as first line therapy. If patient has NYHA class II or III CHF, also consider adding β -blocker therapy ⁴ . |
| LDL-c | <u>LDL-c < 100 mg/dL</u> | No | Elevated LDL-c LDL-c level > 100 mg/dL reported and patient on statin therapy. Recommend either titrating current medication, adding another lipid lowering medication or changing to alternative therapeutic regimen in order to achieve ACC/AHA recommended LDL-c level of < 100 mg/dL ^{1,2} . |
| Triglycerides | <u>Triglycerides < 200 mg/dL</u> | No | Elevated Triglycerides Triglycerides level > 200 mg/dL reported. The ACC/AHA recommends gemfibrozil or niacin therapy for patients with HDL-c < 40 mg/dL and triglycerides level > 200 mg/dL, if no contraindications ^{1,2} . |
| HDL-c | <u>HDL-c > 40</u> | No | Low HDL-c HDL-c level < 40 mg/dL reported. Currently on lipid lowering medication. If accompanying triglycerides levels > 200 mg/dL, the ACC/AHA Recommends gemfibrozil or niacin therapy ^{1,2} . |
| Diabetes | <u>HbA1c < 8%</u> | No | <ul style="list-style-type: none"> Diabetes HbA1c > 8% reported. The ADA recommends a HbA1c goal < 7%. The findings of the DCCT and UKPDS studies indicate that strict blood glucose control will prevent up to 70% of significant, kidney, eye, and neurological complications. These studies also indicate that every percentage point decrease in an individual's HbA1c level there is a 25% reduction in diabetes-related deaths, a 7% reduction in all-cause mortality and an 18% reduction in combined fatal and nonfatal myocardial infarction³. |
| Current Smoker | <u>Non-smoker</u> | Not Known | Smoking Cessation No response received. Assess the patient's smoking status and offer appropriate interventions if currently smoking ⁵ . |
| Obesity | <u>BMI < 27 Kg/m²</u> | No | Regular exercise may reduce the risk of CAD Recommend low cholesterol, low fat diet |

¹AHA/ACC/ACP-ASIM Guidelines for the Management of Patients with Chronic Unstable Angina and Acute MI (2000)

²National Cholesterol Education Program (NCEP – ATPIII) – 2001

³American Diabetes Association 2001

⁴The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI) – 1997

⁵Treating Tobacco Use and Dependence, U.S. Department of Health and Human Services Clinical Guidelines – 2000--